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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,014	10/12/2005	Yasuaki Ito	Q101066	1924
23373 7590 05/13/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER BASU, NIRMAJ SINGH	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 05/13/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/552,014

## Applicant(s)

ITO ET AL.

## Examiner

NIRMAL S. BASI

## Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 11-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S5108)  
Paper No(s)/Mail Date 10/12/2005
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group IX, claim 10, in the reply filed on April 12, 2006 is acknowledged.

Claims 1-9, 11-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

2. CRF and sequence listing filed 5/3/06 has been entered.

3. Drawings filed 10/12/05 are approved by the examiner.

4. Applicant has claimed foreign priority to "JAPAN 2003-122464" but has not provided a translation of the foreign priority document.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Examiner requires an English translation of foreign priority document for the purpose of determining the applicant's right to rely on the foreign filing date.

Appropriate correction is required.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The method does not describe how the receptor protein, its partial peptide or salt thereof and the compound or element or salt thereof are used in conjunction with the changes in binding property of said receptor protein or salt thereof to an ionizable metal element or salt thereof to determine if a substance is an agonist or antagonist to the G-protein coupled receptor. The omitted steps are at least as follows:

(1) contacting the compounds; (2) assaying the binding; (3) identifying the specific changes of binding characteristics; (4) comparison step, (5) differentiation between the agonist and antagonist screening (5) conclusion how the steps achieve the goal of the claim.

Claim 10 is also indefinite because it is not clear which amino acid sequences are considered substantially the same as the sequence represented by SEQ ID NO: 1 so as to allow the metes and bounds of the claim to be determined. The specification does not provide a definition of "substantially the same" as applied to SEQ ID NO: 1 so as to allow the metes and bounds of the claim to be determined. Since a change of a single amino acid in a protein can affect the activity of a protein it is critical that the metes and bounds of the term "substantially the same" be clear so as to allow the metes and bounds of the claim to be determined. There is no definition of "substantially the same" that clarifies how similar sequences must be to be considered "substantially the same" or what activities they must retain to be "substantially the same".

Further the term "represented by" is confusing when referring to SEQ ID NO: 9. The word "represented" can mean "to take the place of in some respect" as well as some other definitions, which could add ambiguity to the claim. It is suggested, to overcome this specific part of the rejection, the term "represented by" be replaced with "of".

***Claim Rejections - 35 USC § 102***

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 10 rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,599,718 (Liu et.al.)

Liu discloses GPCR39 (AF034633) which is 100% identical to the G protein coupled receptor (GPCR) of SEQ ID NO: 1. Liu also discloses various methods of identifying ligands (agonists and antagonists) for the GPCR comprising contacting cells expressing the GPCR with a compound suspected of being a ligand for said receptor and determining whether binding occurs, binding constituting a positive indication of the

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presence of a ligand. The disclosure of Liu meets the limitations of claim 10 absent evidence to the contrary.

#### Advisory

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIRMAL S. BASI whose telephone number is (571)272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nirmal S. Basi/  
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/Gary B. Nickol /

Supervisory Patent Examiner, Art Unit 1646